IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KOWA COMPANY, LTD., KOWA PHARMACEUTICALS AMERICA, INC., and NISSAN CHEMICAL INDUSTRIES, LTD., Plaintiffs, v. APOTEX, INC., and APOTEX CORP., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs, Kowa Company, Ltd. ("KCL"), Kowa Pharmaceuticals America, Inc. ("KPA") (collectively, "Kowa"), and Nissan Chemical Industries, Ltd. ("NCI") by their undersigned counsel, for their Complaint against defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(e)(2) and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(c) and 1400(b). Personal jurisdiction over the defendants in Delaware is proper under 10 *Del. C.* § 3104(c) and because defendants are doing business in this jurisdiction.

Parties

2. KCL is a Japanese corporation having its corporate headquarters and principal place of business in Aichi, Japan. KPA is a wholly owned U.S. subsidiary of KCL. KPA has its

corporate headquarters and principal place of business in Montgomery, Alabama and is organized under the laws of Delaware.

3. NCI is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan.

4. KCL and NCI are engaged in the business of research, developing, manufacturing, and marketing of a broad spectrum of innovative pharmaceutical products, including Livalo®.

5. On information and belief, Apotex, Inc. is a company organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9.

6. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is responsible for sales and marketing of Apotex, Inc. products in the United States. On information and belief, Apotex Corp. also acts as Apotex Inc.'s United States agent for purposes of making regulatory submissions, including ANDAs, to the United States Food and Drug Administration.

7. Upon information and belief, Apotex Inc. has actual control over the activities of Apotex Corp. including Apotex Corp.'s filing of ANDA No. 20-6068.

8. Upon information and belief, Apotex sells generic drugs throughout the United States, including at least in Delaware.

9. Upon information and belief, Apotex is currently transacting business in the District of Delaware, at least by making and shipping into this Judicial District, or by using,

offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products. Upon information and belief, Apotex Corp. distributes drug products manufactured by Apotex, Inc. throughout the United States, including at least in the State of Delaware. Upon information and belief, Apotex derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Delaware and the District of Delaware. By filing its ANDA, Apotex has committed, and unless enjoined, will continue to commit a tortious act without the State of Delaware, which Apotex expects or should reasonably expect to have consequences in the State of Delaware and this Judicial District. In addition, Apotex previously consented to, and availed itself of, this jurisdiction by having filed lawsuits before this United States District Court for the District of Delaware.

The New Drug Application

10. KPA sells drug products containing pitavastatin calcium (the "pitavastatin drug product") under the trade name Livalo® in the United States pursuant to the United States Food and Drug Administration's approval of a New Drug Application ("NDA") held by KCL (NDA No. 22-363).

11. Livalo® is approved for use as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia.

12. The approval letter for Livalo®, with approved labeling, was issued by the FDA on August 3, 2009.

13. Certain amendments to the approved labeling for Livalo® have subsequently been approved.

The Patents in Suit

14. United States Patent No. 8,557,993 ("the '993 patent"), entitled "Crystalline Forms of Pitavastatin Calcium," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on October 15, 2013 to inventors Paul Adriaan Van Der Schaaf, Fritz Blatter, Martin Szelagiewicz, and Kai-Uwe Schoening, and ultimately was assigned to plaintiff NCI. The '993 patent claims, inter alia, crystalline polymorphs or the amorphous form of pitavastatin or processes for preparing the same.

15. Plaintiff NCI has been and still is the owner through assignment of the '993 patent, which expires on February 2, 2024. KCL is NCI's licensee for the '993 patent and KPA holds a license from KCL for the '993 patent.

16. In accordance with its license, KPA sells the pitavastatin drug product under the trade name Livalo® in the United States. Sales of Livalo® are made pursuant to approval by the FDA of NDA No. 22-363.

17. Plaintiff KCL manufactures the Livalo® drug products as sold by KPA.

18. Plaintiffs Kowa and NCI will be substantially and irreparably harmed by infringement of the '993 patent. There is no adequate remedy at law.

COUNT I

INFRINGEMENT OF THE '993 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

19. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

20. Upon information and belief, defendant Apotex filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j) (ANDA No. 20-6068) seeking approval to market 1 mg, 2 mg, and 4 mg tablets comprising pitavastatin calcium.

21. By this ANDA filing, Apotex has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, importation, use, offer for sale, and/or sale, or inducement thereof, of plaintiffs' patented pitavastatin drug product immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Apotex has indicated that its pitavastatin drug product is bioequivalent to Plaintiffs' pitavastatin drug product.

22. By its ANDA filing, Apotex seeks to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' Livalo® pitavastatin drug product prior to the expiration date of the '993 patent.

23. By a letter dated August 18, 2014 (the "Notice Letter"), Apotex informed Kowa and NCI that Apotex had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I). On or about August 19, 2014, KPA received the Notice Letter. On or about August 21, 2014, KCL and NCI received the Notice Letter.

24. Apotex's Notice Letter, purporting to be Apotex's Notice of Certification under 21 U.S.C.§ 355(j)(2)(B)(ii), indicates that Apotex intends to engage in the commercial manufacture, use, or sale of its proposed pitavastatin drug product prior to the expiration of the '993 patent.

25. The Notice Letter asserts that in Apotex's opinion, the '993 patent purportedly is "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Apotex's ANDA."

26. Apotex's filing of ANDA No. 20-6068 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale and/or sale, or

the inducement thereof, of its proposed pitavastatin drug product before the expiration of the '993 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. Apotex's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed pitavastatin drug product will directly infringe or induce infringement of at least one claim of the '993 patent under 35 U.S.C. § 271(e)(2)(A).

28. Unless Apotex is enjoined from infringing the '993 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Apotex's pitavastatin drug product for which it seeks FDA approval or any drug product containing pitavastatin will infringe at least one claim of the '993 patent;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Apotex to commercially make, use, sell, offer to sell or import its pitavastatin drug product or any drug product containing pitavastatin be no earlier than the date following the expiration date of the '993 patent;

(c) a permanent injunction restraining and enjoining against any infringement by defendants, their officers, agents, attorneys, employees, successors or assigns, or those acting in privity or concert with them, of the '993 patent, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Apotex's pitavastatin drug product or any drug product containing pitavastatin, and/or any inducement of the same;

(d) Attorneys' fees in this action under 35 U.S.C. § 285; and

(e) such further and other relief in favor of plaintiffs and against defendants as this Court may deem just and proper.

Dated: October 2, 2014

DLA PIPER LLP (US)

/s/ Denise S. Kraft

Denise S. Kraft (DE No. 2778)
Brian A. Biggs (DE No. 5591)
1201 North Market Street, Suite 2100
Wilmington, DE 19801
Telephone: (302) 468-5645
Facsimile: (302) 778-7917
denise.kraft@dlapiper.com
brian.biggs@dlapiper.com

Attorneys for Plaintiffs
Kowa Company, Ltd.,
Kowa Pharmaceuticals America, Inc., and
Nissan Chemical Industries, Ltd.